510(k) Summary
per 21 CFR §807.92 (c)

JUL - 2 2009

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Stacey A. Strand Regulatory Affairs Specialist II Tel: 763.255.0688 Fax: 763.494.2222 E-mail: strands@bsci.com
Date Prepared	February 26, 2009
Proprietary Name(s)	ACUITY Strait-Trak™ and ACUITY™ Mailman™ venous Guidewires
Common Name	Guide Wire
Product Code	DQX
Classification of Device	Catheter Guidewire Class II, 21 CFR Part 870.1330

Predicate Devices

Boston Scientific ChoICE Extra Support and Mailman PTCA Guidewires	K964551	May 21, 1997
Guidant HI-TORQUE Whisper View Guidewire	K061453	June 22, 2006

Device Description

Boston Scientific ACUITY Strait-Trak and ACUITY Mailman venous Guidewires for Left Ventricular Lead Delivery. These two Boston Scientific Guidewires are hydrophilic coated steerable guidewires available in a 182.2 cm length. The distal tip is shapeable. For product specifications, including wire diameter, length, tip style and radiopaque tip length, please refer to the product label.

Indication for Use	Boston Scientific ACUITY Strait-Trak and ACUITY Mailman venous guidewires are intended to facilitate the placement of Left Ventricular (LV) leads within the Coronary Sinus (CS) vasculature.
Comparison of Technological Characteristics	The ACUITY Strait-Trak and ACUITY Mailman venous guidewires incorporate a substantially equivalent design, packaging, fundamental technology, manufacturing, and sterilization as those featured in the predicate Boston Scientific ChoICE PTCA guidewire family.
Support of Substantial Equivalence	Bench testing was performed to support a determination of substantial equivalence (i.e. tip flexibility, device delivery support, lead compatibility, and guidewire usage) to the predicate BSC ChoICE guidewires. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were identified during device testing. The Indication for Use for the ACUITY Strait-Trak and ACUITY Mailman venous guidewires is substantially equivalent to the Guidant HI-TORQUE Whisper View Guidewire Indications for Use statement.
Conclusion	Based on the Indications for Use, technological characteristics, safety and performance testing, the ACUITY Strait-Trak and ACUITY Mailman venous guidewires have been shown to be appropriate for their intended use and are considered to be substantially equivalent to the Boston Scientific ChoICE PTCA guidewire family (K964551; cleared May 21, 1997).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Boston Scientific Corporation
c/o Ms. Stacey A. Strand
Regulatory Affairs Specialist II
One Scimed Place
Maple Grove, MN 55311

Re: K090554
ACUITY Mailman and ACUITY Strait-Trak Venous Guidewires
Regulation Number: 21 CFR 870. 1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: June 2, 2009
Received: June 3, 2009

Dear Ms. Strand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090554

Device Name: ACUITY Strait-Trak™ and ACUITY™ Mailman™ venous Guidewires

Indications for Use:

Boston Scientific ACUITY Strait-Trak and ACUITY Mailman Venous Guidewires are intended to facilitate the placement of Boston Scientific or Guidant Left Ventricular (LV) leads within the Coronary Sinus (CS) vasculature.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090554